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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,214	03/25/2004	Fiona E. Black	01-00007	2483

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EXAMINER

LUM, LEON YUN BON

ART UNIT PAPER NUMBER

1641

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,214

Applicant(s)

BLACK ET AL.

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-11 and 34-60 is/are pending in the application.
- 4a) Of the above claim(s) 38-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,8-11 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20051219</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The amendment filed 29 September 2005 is acknowledged and has been entered.

Election/Restrictions

2. Applicant's election with traverse of claims 38-60 in the reply filed on 29 September 2005 is acknowledged. The traversal is on the ground(s) that newly added claims 38-60 are based on non-elected claims 12-33 and are dependent upon elected claim 1. This is not found persuasive because process claims 12-33 were restricted based upon claiming a different invention from the product of claim 1. Since newly added claims 38-60 have essentially the same claim language as claims 12-33, they are also considered to be in a different group from claim 1. Although claims 38-60 are dependent upon claim 1, the difference in claimed subject matter (i.e. product vs. process) enables restriction between claims 1 and 38-60 to be proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 8-9, 11, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodenhamer (US 6,051,388).

Bodenhamer reference teaches a polyethylene film with immobilized capture agents thereon (i.e. flat surface with covalently attached biopolymer probes; chip) and an agarose gel layer over the immobilized capture agents (i.e. stabilization layer coats biopolymer probe; agarose), wherein the capture agents are antibodies (i.e. biopolymer probe comprises a polypeptide) or single stranded nucleic acid probes (i.e. biopolymer probe comprises a polynucleotide), and wherein the layer of immobilized capture agents can include a plurality of different types of capture agents (i.e. array of different biopolymer probes). See column 5, line 28 to column 6, line 20; and Figures 1, 2-2A, and 7-7A.

With respect to claims 34-35, Bodenhamer teaches analyte detection using a detector antibody that forms a sandwich with the analyte and immobilized antibody (i.e. probes lack extrinsic labels). See Figure 4.

With respect to claims 36-37, Bodenhamer teaches immobilized capture agents such as ligands conjugated with dyes, wherein a conformational change produced by ligand-analyte binding induces the dyes to produce a visual cue (i.e. probes comprise extrinsic labels). See column 7, lines 35-45.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodenhamer (US 6,051,388) in view of Arai et al (US 5,004,685).

Bodenhamer reference has been disclosed above, but fails to teach that the stabilization polymer is non-naturally occurring.

However, Applicants have not disclosed that the specific limitation of a non-naturally occurring stabilization polymer is for any particular purpose or to solve any stated problem. In terms of the novelty of the claimed invention, it seems as if a non-naturally occurring stabilization polymer is functionally equivalent to one that occurs naturally. This is supported by Arai et al reference, which specifically discloses that agarose (i.e. naturally occurring polymer) is equivalent in function to polyvinyl alcoholol and polyvinyl pyrrolidone (i.e. non-naturally occurring polymer) when applied as a coating on a polyethylene glycol-based support. See column , lines 42-58 and column 10, lines 31-34.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a non-naturally occurring stabilization polymer for the agarose gel of Bodenhamer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in substituting a non-naturally occurring polymer such as polyvinyl alcoholol or polyvinyl pyrrolidone for the agarose of Bodenhamer, since Bodenhamer teaches that the agarose is coated onto a polyethylene support, and Arai

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et al disclose that both polyvinyl alcohol and polyvinyl pyrrolidone can be applied onto polyethylene-based supports.

Response to Arguments

9. Applicant's arguments with respect to claim 1, 3, 6, 8-11, and 34-37 have been considered but are moot in view of the cancellation of claim 3 and the new ground(s) of rejection.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641



LYL



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12/22/05